K030987

8.0 510 (k) Summary

1.0 Name and address of Submitter

Pelican Products, Inc.
2248 Highway 43 North
Pelahatchie, MS 39145c

JUN 12 2003

Contact Person

James Hemphill Jr.
Tel.: 601-854-6777
Fax 601-854-6998

Date Prepared 3/26/03

2.0 Name of Device

- **Trade Name**:
  #500/600 (deep well lens case with integral lids)
  #700 (ultra clear single lens case with cap)
  #750/750U (billboard lens case with caps)
  #800 (curved lens case with caps)
  #900G (lens vial w/gasket and cap)

- **Classification Name**: Contact Lens Storage Case

3.0 Indications

Storage of soft (hydrophilic)/rigid gas permeable and hard contact lenses during chemical disinfection. Use during chemical disinfection only.
DO NOT USE WITH HEAT

4.0 Device Description

The Pelican Products, Inc contact lens storage cases are intended for use for storage of soft, hard and rigid gas permeable contact lenses during chemical disinfection. Not to be used for heat disinfection.

5.0 Substantially Equivalent:

Pelican Products, Inc. contact lens storage cases are substantially equivalent in terms of indication for use and safety and effectiveness to the Alcon contact Lens Case.

6.0 Summary of Safety and Effectiveness

Cytotoxicity, systemic toxicity and ocular irritation studies were performed to assess the safety and effectiveness of the Pelican Products, Inc in accordance with the guidelines set forth in the FDA'S Guidance document titled " Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.

The test results showed no evidence of cellular or systemic toxicity, or ocular irritation.

7.0 Conclusion

The Pelican Products, Inc contact lens storage case are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2003

Pelican Products, Inc.
c/o Ms. Carol Noble
Horizon Consulting
611 Eisenhauer Street
Grand Junction, CO 81505

Re: K030987
Trade/Device Name: Contact Lens Storage Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (hydrophilic) contact lens care products
Regulatory Class: Class II
Product Code: LRX
Dated: March 26, 2003
Received: March 28, 2003

Dear Ms. Carol Noble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5.0 INDICATIONS FOR USE STATEMENT

Device Name:

- #500/600 (deep well lens case with integral lids)
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Indication of Use:

Storage of soft (hydrophilic)/rigid gas permeable and hard contact lenses during chemical disinfection. Use during chemical disinfection only.
DO NOT USE WITH HEAT

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use X
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

Daniel W. C. Brown, PH.D.
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K030987